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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,917	10/23/2003	Ruchika Singhal	1023-234US01	6514
28863 7590 12/28/2007 SHUMAKER & SIEFFERT, P. A. 1625 RADIO DRIVE SUITE 300 WOODBURY, MN 55125			EXAMINER KAHELIN, MICHAEL WILLIAM	
			ART UNIT 3762	PAPER NUMBER
			NOTIFICATION DATE 12/28/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@ssiplaw.com

Office Action Summary

Application No.

10/691,917

Applicant(s)

SINGHAL ET AL.

Examiner

Michael Kahelin

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-19,23-38 and 42-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-19,23-38 and 42-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 20071119.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 6, 8-13, 19, 23, 27-30, 35, 36, 38, 43-46, 50, 52, and 54-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Meadows et al. (US 6,381,496, hereinafter "Meadows").
3. In regards to claims 1, 6, 19, 23, 27, 38, 55, and 56, Meadows discloses monitoring the output of a posture sensor and defining an event based on the monitoring of the sensor output (col. 17, line 66; "e.g. horizontal"); monitoring therapy, generating therapy information, and associating therapy information with the event (col. 19, lines 1-19; the "OPS" defined by the patient is monitored, saved, and associated with the event); and subsequently detecting the defined event and automatically providing therapy to the patient accordingly (col. 18, lines 6-12; the "OPS" defined by the patient and associated with an event is provided).
4. In regards to claims 8, 9, 10, 28, 29, 43, 44, and 45, generating therapy information comprises recording the value/change to a parameter of a therapy parameter, over the time period that the patient is operating the programmer (col. 18, line 55-col. 19, line 19).

5. In regards to claims 11, 30 and 46, the therapy can be delivered based on a combination of events, two of which are an elapsed time and posture change (col. 18, line 5).
6. In regards to claims 12 and 36, the change to the parameter is made with a programming device (Fig. 8).
7. In regards to claims 13 and 35, the parameter is one of amplitude, pulse width, and pulse rate of a neurostimulator (col. 19, line 16).
8. In regards to claims 50, 52, and 54, the device controls pain (col. 1, line 12).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 5, 7, 14-18, 24-26, 31-34, 37, 42, 47-49, 51, and 53 rejected under 35 U.S.C. 103(a) as being unpatentable over Meadows. Meadows discloses the essential features of the claimed invention except for determining position with a multi-axis accelerometer; defining the event by recording the sensor over a period of time; receiving the time delay parameter/command to enter a learning mode from a user; suspending therapy based on the event; or presenting the defined event in a timing diagram to a clinician as diagnostic data. It is well known in the art to determine position with multi-axis accelerometers to determine activity or posture with an inexpensive, off-the-shelf component; to define an event by recording a sensor over time to customize events to a particular patient/implantation configuration; to receive various parameters or commands (such as the time delay of Meadows' col. 18, line 2) from a user to provide customized therapy; to suspend therapy based on events to conserve battery power when therapy is not needed; and to present events on timing diagrams to clinicians to allow the clinician to modify device parameters to effectuate ideal therapies. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Meadows' invention by providing a means to determine position with multi-axis accelerometers to determine activity or posture with an inexpensive, off-the-shelf component; to define an event by recording a sensor over time to customize events to a particular patient/implantation configuration; to receive various parameters or commands from a user to provide customized therapy; to suspend therapy based on events to conserve battery power when therapy is not

needed; and to present events on timing diagrams to clinicians to allow the clinician to modify device parameters to effectuate ideal therapies.

Response to Arguments

12. Applicant's arguments filed 10/9/2007 have been fully considered but they are not persuasive. Applicant argued that Meadows' invention is pre-programmed to recognize certain events, and deliver therapy according to an operational parameter set that was programmed for the event, thus does not define an event based on the monitoring of sensor output nor generate therapy information based on the monitoring of the therapy, as claimed. However, the Examiner maintains that the claim amendments do not avoid the disclosed features of Meadows' invention. When Meadows' invention determines, e.g., that a person is horizontal, it defines an event (that the patient is horizontal) based on the monitoring of the sensor output (the position sensor). In other words, Meadows' invention may or may not "define," in the first (ex ante) sense; as in deriving a definition of a certain *type of events* (i.e., "if the sensor reads X, then the device will hereafter assert, or define, that the patient is horizontal"). But Meadows' invention does "define" an individual event in a second (ex post) sense; as in recognizing a *specific event* as being one of a certain type of event (i.e. "since the sensor reads X, the device will define this particular event as the patient being horizontal"). Further, Meadows' monitors the therapy delivered by the medical device during occurrence of the defined event because it monitors and saves the therapy parameters that the patient or physician has selected, per column 19. Initial OPS's are

set, the patient is free to change those OPS's while the device monitors and saves the changes, and the updated OPS's are used to stimulate upon detection of the defined events (col. 18, line 8).

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

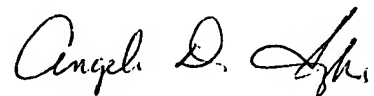
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

Application/Control Number:
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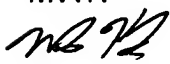
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



ANGELA D. SYKES
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12/15/07